(3) Each lawfully recognized collective bargaining representative or other representative of the employees of the employer or public entity.

(f) *Reimbursement of enrollees for services improperly denied, or for charges improperly imposed.* (1) If CMS determines, under paragraph (c)(1) of this section, that an HMO is out of compliance, CMS may require the HMO to reimburse its enrollees for the following—

(i) Expenses for basic or supplemental health services that the enrollee obtained from other sources because the HMO failed to provide or arrange for them in accordance with its assurances.

(ii) Any amounts the HMO charged the enrollee that are inconsistent with its assurances. (Rules applicable to charges for all enrollees are set forth in §§ 417.104 and 417.105. The additional rules applicable to Medicare enrollees are in § 415.454.)

(2) This paragraph applies regardless of when the HMO failed to comply with the appropriate assurances.

(g) *Remedy: Civil suit*—(1) *Applicability.* This paragraph applies to any HMO or other entity to which a grant, loan, or loan guarantee was awarded, as set forth in subpart V of this part, on the basis of its assurances regarding the furnishing of basic and supplemental services or its operation and organization, as the case may be.

(2) *Basis for action.* If CMS determines that the HMO or other entity has failed to initiate or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, CMS may bring civil action in the U.S. district court for the district in which the HMO or other entity is located, to enforce compliance with the assurances it gave in applying for the grant, loan, or loan guarantee.

[59 FR 49841, Sept. 30, 1994]

§ 417.164 Effect of revocation of qualification on inclusion in employee's health benefit plans.

When an HMO's qualification is revoked under § 417.163(d), the following rules apply:

(a) The HMO may not seek inclusion in employees health benefits plans under subpart E of this part.

(b) Inclusion of the HMO in an employer's health benefits plan—

(1) Is disregarded in determining whether the employer is subject to the requirements of subpart E of this part; and

(2) Does not constitute compliance with subpart E of this part by the employer.

[59 FR 49842, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

§ 417.165 Reapplication for qualification.

An entity whose qualification as an HMO has been revoked by CMS for purposes of section 1310 of the PHS Act may, after completing the corrective action required under § 417.163(c)(2), reapply for a determination of qualification in accordance with the procedures specified in subpart D of this part.

[43 FR 32255, July 25, 1978. Redesignated at 52 FR 36746, Sept. 30, 1987, and amended at 58 FR 38078, July 15, 1993]

§ 417.166 Waiver of assurances.

(a) *General rule.* CMS may release an HMO from compliance with any assurances the HMO gives under subpart D of this part if—

(1) The qualification requirements are changed by Federal law; or

(2) The HMO shows good cause, consistent with the purposes of title XIII of the PHS Act.

(b) *Basis for finding of good cause.* (1) Grounds upon which CMS may find good cause include but are not limited to the following:

(i) The HMO has filed for reorganization under Federal bankruptcy provisions and the reorganization can only be approved with the waiver of the assurances.

(ii) State laws governing the entity have been changed after it signed the assurances so as to prohibit the HMO from being organized and operated in a manner consistent with the signed assurances.

(2) Changes in State laws do not constitute good cause to the extent that the changes are preempted by Federal law under section 1311 of the PHS Act.

(c) *Consequences of waiver.* If CMS waives any assurances regarding compliance with section 1301 of the PHS Act, CMS concurrently revokes the